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SERIAL NUMBER	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
07/533,294	06/05/90	SOMMERMEYER	K LUDR3.0-036

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EXAMINER  
NUTTER, N

ART UNIT PAPER NUMBER  
1503 6

DATE MAILED: 02/20/92

This is a communication from the examiner in charge of your application.  
COMMISSIONER OF PATENTS AND TRADEMARKS

- ☐ This application has been examined. ☒ Responsive to communication filed on 16 Dec 1991. ☐ This action is made final.
- A shortened statutory period for response to this action is set to expire 3 month(s), — day(s) from the date of this letter.  
Failure to respond within the period for response will cause the application to become abandoned. 35 U.S.C. 133

Part I THE FOLLOWING ATTACHMENT(S) ARE PART OF THIS ACTION:

- |   |   |
|---|---|
| 1. <input type="checkbox"/> Notice of References Cited by Examiner, PTO-892.        | 2. <input type="checkbox"/> Notice re Patent Drawing, PTO-848.                  |
| 3. <input type="checkbox"/> Notice of Art Cited by Applicant, PTO-1449.             | 4. <input type="checkbox"/> Notice of Informal Patent Application, Form PTO-152 |
| 5. <input type="checkbox"/> Information on How to Effect Drawing Changes, PTO-1474. | 6. <input type="checkbox"/> _____   |

Part II SUMMARY OF ACTION

1. ☒ Claims 1 - 11 are pending in the application.  
Of the above, claims 4 - 7 are withdrawn from consideration.
2. ☐ Claims \_\_\_\_\_ have been cancelled.
3. ☐ Claims \_\_\_\_\_ are allowed.
4. ☒ Claims 1-3 and 8-11 are rejected.
5. ☐ Claims \_\_\_\_\_ are objected to.
6. ☐ Claims \_\_\_\_\_ are subject to restriction or election requirement.
7. ☐ This application has been filed with informal drawings under 37 C.F.R. 1.85 which are acceptable for examination purposes.
8. ☐ Formal drawings are required in response to this Office action.
9. ☐ The corrected or substitute drawings have been received on \_\_\_\_\_ Under 37 C.F.R. 1.84 these drawings are ☐ acceptable; ☐ not acceptable (see explanation or Notice re Patent Drawing, PTO-848).
10. ☐ The proposed additional or substitute sheet(s) of drawings, filed on \_\_\_\_\_, has (have) been ☐ approved by the examiner; ☐ disapproved by the examiner (see explanation).
11. ☐ The proposed drawing correction, filed \_\_\_\_\_, has been ☐ approved; ☐ disapproved (see explanation).
12. ☐ Acknowledgement is made of the claim for priority under U.S.C. 119. The certified copy has ☐ been received ☐ not been received ☐ been filed in parent application, serial no. \_\_\_\_\_; filed on \_\_\_\_\_.
13. ☐ Since this application appears to be in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1835 C.D. 11; 453 O.G. 213.
14. ☐ Other

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Applicant's election with traverse of Group I, claims 1-3 in Paper No. 4 is acknowledged. The traversal is on the ground(s) that the product cannot be made by any other process, in particular the process of GB 1 395 777 and that the process of Group II could not be employed to make other products. Further, "(t)he possibility of different classification of the groups of claims does not require the conclusion".. This is not found persuasive because the process could indeed be employed to produce a materially different product the process could indeed be employed to produce a materially different product such as an hydroxyethylated polysaccharide, e.g. cellulose. Further the GB 1 395 777 teaches a  $C_2 - C_4$  molar ratio of 0.5-2.0 which is equivalent to 5-20, and embraces that of the Group II claims.

The requirement is still deemed proper and is therefore made FINAL.

Claims 8-11 are deemed to be linking claims, which link Group I and Group II.

The rejection of claims 1-3 under 35 U.S.C. 103 as obvious over Nitsch et al. is hereby expressly withdrawn.

The following is a quotation of 35 U.S.C. § 103 which forms the basis for all obviousness rejections set forth in this Office action:

A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary

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shall in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Subject matter developed by another person, which qualifies as prior art only under subsection (f) or (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.

Claims 1-3 and 8-11 are rejected under 35 U.S.C. § 103 as being unpatentable over Mitsch et al. taken with Staley Manufacturing (GB 935,339) and Morishita Pharmaceutical (GB 1 395 977).

The reference to Mitsch et al. teaches the production of an hydroxyethyl starch useful as a plasma expander which may include starch derivatives having molecular weights in the range of, preferably, 200,000 to 450,000 Daltons, which lies within the range recited by applicants in the instant claims. Note column 2 (lines 21-24). At column 3 (lines 25-28) for a molar substitution of 0.1 to 0.8. The reference teaches hydrolysis of amylopectin rich starch followed by hydroxyethylation. Note column 2 (lines 38-43) which teaches hydrolytic decomposition, to adjust the starch/ product to an acceptable molecular weight, as set out at column 3 (lines 21-24). Note column 2 (lines 44 et seq) which teaches the employment of an alkylene oxide in the presence of alkali for the etherification. Note the paragraph bridging column 2 to column 3 for the purification of the

product. Finally, note the conversion step of producing a dry powder by spray drying at column 3 (lines 8-20). The process steps are deemed to be conventional.

The reference to Staley Manufacturing (GB 935,329) teaches the production of an hydroxyethyl starch derivative which has a molar substitution greater than 0.15 at page 1 (lines 52-60). The patent further teaches that specific molar amounts of etherification agent must be present to achieve specific molar substitution is dependent and manipulable relative to the amounts of etherification agent employed at page 3 (lines 12-32). Further, note Tables I and II at pages 6 and 7.

The British patent to Morishita Pharmaceutical teaches the production of "a hydroxyethyl starch having a molar ratio between the resulting hydroxyl group at the 2-position and those at the 6-position of 0.5 to 2.0 (or 5 to 20)" at page 1 (lines 6-8). Further, at page 2 (lines 21-28) the patent teaches the manipulation of the ratio as being dependent on varying the amounts of alkali relative to the  $C_2$  to  $C_6$  disclosed by the reference embraces that of the instant claims.

The primary reference to Nitsch et al. teaches the production of an hydroxyethyl starch from hydrolyzed amylopectin rich starch essentially as recited in the instant claims, except for the specific molar substitution and  $C_2$  to  $C_6$  ratio recited. The British patent to Staley, also drawn to production of an

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hydroxyethyl starch teaches that it is known how to manipulate the molar substitution of hydroxyethyl starch. Finally, the British patent to Morishita Pharmaceutical, likewise drawn to production of an hydroxyethyl starch, teaches that it is known how to manipulate the  $C_2$  to  $C_1$  ratio of substitution. All references are drawn to hydroxyethyl starch production. The compounds of the claims are employed in the identical capacities as those of Nitsch et al.. Thus, the production of an hydroxyethyl starch plasma extender as recited in the instant claims would have been obvious from the teachings of the references to a practitioner having an ordinary skill in the art at the time the invention was made. No surprising or unexpected results have been shown on the record.

Applicant's arguments with respect to claims 1-3 have been considered but are deemed to be moot in view of the new grounds of rejection.

The Declaration under 37 C.F.R. 5 1.132 filed 20 December 1991 is insufficient to overcome the rejection of claims 1-3 based upon Nitsch et al. as set forth in the last Office action because the Declaration is not germane to the rejection at issue. Note MPEP 716.

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Due to the new grounds of rejection this action is not being  
made FINAL

Nutter:css  
February 19, 1992

A handwritten signature in cursive script, reading "Nathan M. Nutter". The signature is written in dark ink and is positioned to the right of the typed name.

**NATHAN M. NUTTER  
PATENT EXAMINER  
ART UNIT 153**